UNITED STATES DISTRICT COURT NORTHERN DISTRICT OF OHIO

THE PALA BAND OF MISSION INDIANS; INDIAN HEALTH COUNCIL, INC.;

Plaintiffs,

vs.

MCKINSEY & COMPANY, INC.,

Defendant.

Member Case No. 1:21-op-45052

COMPLAINT

JURY TRIAL DEMANDED

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I. INTRODUCTION

- 1. This case arises from the worst man-made epidemic in modern medical history—the misuse, abuse, and over-prescription of opioids. This crisis arose from the opioid manufacturers' deliberately deceptive marketing strategy to expand opioid use.
- 2. McKinsey and Company, Inc. ("McKinsey" or "Defendant"), played an integral role in creating and deepening the opioid crisis.
- 3. In the years following Purdue Pharma L.P.'s ("Purdue") 2007 guilty plea for misleadingly marketing OxyContin, McKinsey worked closely with Purdue to dramatically increase OxyContin sales to the benefit of McKinsey, Purdue, and the Sackler family, the wealthy family that has owned and controlled Purdue for decades. McKinsey specifically sought to maximize OxyContin sales by working around the requirements of the Corporate Integrity Agreement that Purdue entered as part of its guilty plea. McKinsey also performed related work for other manufacturers of opioids, including Johnson & Johnson. Through the conduct described in this complaint, McKinsey participated in and helped orchestrate a broad scheme to deceptively market opioids.
- 4. McKinsey knew of the dangers of opioids and of Purdue's prior misconduct but nonetheless advised Purdue to improperly market and sell OxyContin, supplying granular sales and marketing strategies and remaining intimately involved throughout implementation of those strategies. McKinsey's actions resulted in a surge in sales of OxyContin and other opioids that fueled and prolonged the opioid crisis.
- 5. Through a series of agreements, McKinsey recently settled opioid-related claims with 49 states (including California), the District of Columbia, and five U.S. territories.
- 6. Plaintiffs are the Pala Band of Mission Indians ("Tribe") and Indian Health

 Council, Inc. (IHC). The Tribe is a federally recognized, sovereign Indian tribe responsible for

 COMPLAINT

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the health and well-being of its citizens. IHC is an inter-tribal consortium and Tribal Organization responsible for providing healthcare services to the citizens of its constituent Tribes, which include the Pala Band of Mission Indians. Native Americans have disproportionately borne the toll of the opioid crisis. Plaintiffs bring this suit to hold McKinsey responsible for its role in that crisis, which has posed an existential threat to tribes and tribal communities.

- 7. The Tribe brings this action in its own proprietary capacity and pursuant to its parens patriae authority to protect the health, safety, and welfare of its citizens to stop the opioid epidemic in California.
- 8. IHC brings this action in its proprietary capacity and pursuant to its interests in protecting the health, safety, and welfare of the citizens of its constituent Tribes to stop the opioid epidemic in California.
- 9. Plaintiffs seek to recover damages and other redress from harm caused by McKinsey's improper marketing practices and other unlawful conduct related to prescription opioids.

II. JURISDICTION AND VENUE

- 10. This Court has subject matter jurisdiction over this action because the Plaintiffs bring a federal cause of action that raises a federal question pursuant to 28 U.S.C. § 1331 and because this action is brought by an Indian tribe pursuant to 28 U.S.C. § 1362. The Court also has supplemental jurisdiction over the Plaintiffs' state law claims pursuant to 28 U.S.C. § 1367 because the state law claims are part of the same case or controversy.
- 11. This Court has personal jurisdiction over Defendant because at all relevant times, McKinsey has purposely availed itself of the privilege of doing business in the State of Ohio, including by engaging in the business of researching, designing, and implementing - 2 -

marketing and promoting strategies for various opioid manufacturers, including Purdue, in support of their sales and marketing of opioids in Ohio.

Ohio under 28 U.S.C. § 1391(g) and 18 U.S.C. § 1965 and pursuant to paragraph 6(a) of Case Management Order 1, issued by this Court on April 11, 2018 in case number 1:17-CV-2804. Plaintiffs hereby asserts that, but for that Order permitting direct filing in this district, Plaintiffs would have filed their cases in the U.S. District Court for the Southern District of California, because a substantial part of the events or omissions giving rise to this action occurred in California and because the Defendant is subject to the jurisdiction of the United States District Court for the Southern District of California. Defendant purposely availed itself of the privilege of doing business in the State of California and in the Southern District of California, including by engaging in the business of researching, designing, and implementing marketing and promoting strategies for various opioid manufacturers, including Purdue, in support of their sales and marketing of opioids in California.

III. PARTIES

A. Plaintiff Indian Tribe

13. Plaintiff Pala Band of Mission Indians ("Tribe") is a federally recognized sovereign Indian nation, with its principal business address in Pala, California. The Tribe exercises inherent governmental authority on behalf of the Tribe itself and its citizens. The Tribe is located in northern San Diego County on a 12,273-acre reservation. The Tribe has 1,143

enrolled citizens who are Cupeño¹ and Luiseño Indian.² A majority of the Tribe's citizens live on the Tribe's Reservation.

- 14. The Tribe is governed by a six-member Executive Committee, acting pursuant to its inherent sovereignty and a constitution adopted by its General Council in November 1994 and certified by the BIA Pacific Region in 1997.
- 15. The Tribe provides a wide range of public safety and community services and programs, including law enforcement, a fire department, a Tribal Court, social services, a post office, pre-school and learning, and programs for its Senior and Veteran citizens. The Tribe also operates the Pala Casino Resort and Spa, under the provisions of the Indian Gaming Regulatory Act (Pub. L. 100–497, 25 U.S.C. § 2701 *et seq.*). The Tribe uses proceeds from its gaming and hospitality enterprises to fund social services and education for its citizens as well as infrastructure improvements to the Reservation, including firefighter and paramedic services and a 24-hour on-site ambulance.
- 16. This action is brought by the Tribe in the exercise of its authority as a sovereign government, in its proprietary capacity, and under its *parens patriae* authority in the public

¹ The word Cupeño is of Spanish derivation, adopting the native place-name Kupa and appending Spanish—"eño" to mean a person who lives in or hails from Kupa. The Cupeños, however, called themselves Kuupangaxwichem, or "people who slept here." The Cupans once occupied territory in a mountainous region at the headwaters of the San Luis Rey River in the valley of San Jose de Valle. Many of the Pala Indians trace their heritage back to Cupa. Today, more than 90 years after having been expelled from their native homeland, the Cupeños call Pala home and live as one among the Luiseño Tribe.

² The Luiseño, or Payómkawichum ("People of the West"), are a Native American people who at the time of the first contacts with the Spanish in the 16th century inhabited the coastal area of southern California, ranging 50 miles from the present-day southern part of Los Angeles to the northern part of San Diego County, and inland 30 miles. The Tribe was named Luiseño by the Spanish due to their proximity to the Mission San Luis Rey de Francia. Today there are six federally recognized Tribes of Luiseño bands based in southern California, including the Pala Band, all with reservations.

interest to protect the health, safety, and welfare of all Tribal citizens and residents of the Tribe's lands.

17. The Tribe has standing to recover damages incurred as a result of Defendant's actions and omissions. The Tribe has standing to bring all claims pled herein, including, *inter alia*, to bring claims under the federal RICO statutes, pursuant to 18 U.S.C. § 1961(3) ("persons" include entities which can hold legal title to property) and 18 U.S.C. § 1964 ("persons" have standing).

B. Plaintiff Tribal Organization

- 18. Plaintiff Indian Health Council, Inc. ("IHC" or "Tribal Organization"), is an intertribal health consortium and Tribal Organization in San Diego County, California, providing health care services to American Indians and Alaska Natives, and to other eligible individuals in the State of California, pursuant to Title V of the Indian Self-Determination and Education Assistance Act (ISDEAA), 25 U.S.C. §§ 5301, et seq., and agreements with the Department of Health and Human Services through its Indian Health Service (IHS). The ISDEAA authorizes tribes and tribal organizations like IHC to enter into contracts and compacts to assume responsibility to provide programs and services that the federal government would otherwise be obligated to provide for the benefit of American Indians and Alaska Natives. IHC's compact is its governing agreement, entered into between IHC and the IHS pursuant to Title V of the ISDEAA, which authorizes IHC to operate health and health-related programs formerly operated by the IHS. In addition, IHC enters into a separate funding agreement with the IHS that governs' the scope of programs and services to be performed.
- 19. The vast majority of the IHS's responsibility for healthcare in California has been compacted by tribes and intertribal consortia like IHC for administration and operation of program and services.

- 20. IHC is a non-profit health consortium of nine Indian Tribes in the northern part of San Diego County,³ serving the health and related needs of the citizens of its Member Tribes and the residents of North County San Diego with its principal place of business on the Rincon Reservation in Valley Center, California. IHC was created in 1970 as a successor to an unincorporated association known as the Pauma Valley Indian Health Project. As such, it is one of the oldest intertribal health consortiums in the nation.
- 21. IHC currently provides health care services and programs to over 5,000 clients, the vast majority of whom are Native American or Alaska Native. IHC provides additional services to nearly 10,000 people, including cultural events, prevention, child welfare services, counseling, and other community-based programs.
- 22. IHC operates two clinics: its main clinic in Valley Center, CA, and a second, smaller clinic on the Santa Ysabel Reservation in Santa Ysabel, CA.
- 23. IHC's facilities provide an array of services including direct medical, dental, and behavioral health care; mammography services; prevention and wellness services; OB/GYN services; cardiological services; eye care; and pharmaceuticals. IHC provides access to primary and preventive care services. It also employs behavioral health clinicians and/or Community Family Service workers to provide on-site mental health and substance abuse services, as well as crisis intervention, domestic violence assistance, and support groups.

³ The IHC is a consortium of the following Tribes: Iipay Nation of Santa Ysabel; Inaja Band of Diegueño Mission Indians of the Inaja and Cosmit Reservation; La Jolla Band of Luiseño Indians; Los Coyotes Band of Cahuilla and Cupeño Indians; Mesa Grande Band of Diegueño Mission Indians of the Mesa Grande Reservation; Pala Band of Mission Indians; Pauma Band of Luiseño Mission Indians of the Pauma & Yuima Reservation; Rincon Band of Luiseño Mission Indians of the Rincon Reservation; and, the San Pasqual Band of Diegueño Mission Indians. All Tribes appear on the list of Indian Entities Recognized and Eligible to Receive Services from the United States Bureau of Indian Affairs ("Tribal List"), published pursuant to Section 104 of the Act of November 2, 1994 (Pub. L. No. 103-454, 108 Stat. 4791, 4792).

- 24. IHC serves IHS beneficiaries as well as non-beneficiaries. Non-beneficiaries are billed for services through their insurance or on a fee-for-service basis.
- 25. IHC serves high-needs populations with limited resources, including in remote areas where access to other providers may not exist or would require a long trip over mountainous terrain into larger cities. The diversion of funding to address a public health crisis like the opioid epidemic, including associated overhead and administrative costs, can have devastating impacts on the ability of IHC to provide an adequate level of basic health care and other needed specialty care in these areas, to meet its obligations under the ISDEAA and agreements with the IHS, and to carry out its organizational missions.
- 26. IHC has standing to recover damages incurred because of Defendant's actions and omissions. IHC has standing to bring all claims pled herein, including, *inter alia*, to bring claims under the federal RICO statutes, pursuant to 18 U.S.C. § 1961(3) ("persons" include entities which can hold legal title to property) and 18 U.S.C. § 1964 ("persons" have standing).

C. Defendant

- 27. Defendant McKinsey and Company, Inc., is a corporation organized under the laws of the state of New York. McKinsey's principal place of business is located at 711 Third Avenue, New York, NY 10017.
- 28. McKinsey is a worldwide management consultant company. From approximately 2004-2019, McKinsey provided consulting services to Purdue Pharma L.P., working to maximize sales of OxyContin and knowingly perpetuating the opioid crisis. McKinsey has provided related consulting services to other manufacturers of opioids.

IV. FACTUAL ALLEGATIONS COMMON TO ALL CLAIMS

A. The Corporate Integrity Agreement

- 29. In May of 2007, Purdue Frederick Company, the parent company of Purdue Pharma L.P. ("Purdue"), pleaded guilty to charges for misleading regulators, doctors, and the public regarding Purdue's opioid OxyContin. In pleading guilty, Purdue admitted to falsely marketing OxyContin as a less addictive, safer alternative to other pain medications.
- 30. In the global settlement resolution, Purdue and its parent company paid over \$600 million and entered into a Corporate Integrity Agreement with the U.S. Department of Health and Human Services Office of Inspector General.
- 31. Under the Corporate Integrity Agreement, for five years, Purdue was required to refrain from making any deceptive or misleading claims about OxyContin and was obligated to submit regular compliance reports regarding its sales and marketing practices. Purdue was also required to monitor, report, and attempt to prevent inappropriate prescribing practices.

B. McKinsey's Role Following the Corporate Integrity Agreement

- 1. The Sacklers seek to divert money to themselves.
- 32. The Sackler family is among the richest families in the United States. Members of the Sackler family have controlled Purdue at all times relevant to this Complaint.
- 33. Following the guilty plea, the Sacklers sought to insulate themselves from the risk they perceived in Purdue. Email threads between the Sacklers in early 2008 indicate that the Sacklers had become concerned about personal liability regarding opioid-related misconduct.
- 34. The Sacklers considered selling Purdue or merging with another pharmaceutical company as an option for limiting their risk. Mortimer Sackler Jr. advocated for a sale or merger in a February 21, 2008 email to Dr. Richard Sackler (a former president and co-chairman of Purdue) and several others, writing:

The pharmaceutical industry has become far too volatile and risky for a family to hold 95% of its wealth in. It simply is not prudent for us to stay in the business given the future risks we are sure to face and the impact they will have on the shareholder value of the business and hence the family's wealth.

The risk he referred to was, at least in significant part, further liability related to misconduct in the marketing and sale of OxyContin.

- 35. Alternatively, the Sacklers considered extracting as much wealth as possible from Purdue through distributions to themselves as shareholders. Such distributions would allow the Sacklers to diversify their assets and make their wealth less vulnerable to judgments regarding Purdue's sales and marketing of opioids, including OxyContin.
- 36. Either option—a sale or significant distributions to shareholders—would require Purdue to increase profitability in the short term. Purdue turned to McKinsey, with which it had an existing business relationship, for help maximizing sales of OxyContin given the requirements of the Corporate Integrity Agreement and the scrutiny that came along with it.
 - 2. <u>McKinsey Supplied Purdue with Granular Sales and Marketing Strategies</u> and Remained Intimately Involved in Implementation.
- 37. McKinsey touts its model of engaging in transformational partnerships with its clients. Rather than giving one-off advice, McKinsey learns each client's business intimately and provides tailored, granular strategies.
- 38. McKinsey had begun collaborating with Purdue by June 2009. McKinsey was tasked with increasing OxyContin sales despite the Corporate Integrity Agreement, which required, among other things, that Purdue comport with FDA requirements, and also included increased review and reporting obligations.
- 39. McKinsey provided sales and marketing strategies designed to sell as much OxyContin as possible, at one point in 2010 telling Purdue that the new strategies McKinsey had developed could generate as much as \$400,000,000 in additional annual sales. McKinsey

worked with Purdue to implement the strategies, with McKinsey's ongoing and extensive involvement.

- 40. OxyContin sales grew dramatically, and the Sacklers diverted the resulting profits into other holdings.
- 41. In a 2009 report, among other sales strategies, McKinsey advised Purdue sales representatives to push the highest dosages of OxyContin, which were the most profitable for Purdue. In order to maximize dosages and improve targeting of the coordinated marketing strategy, McKinsey investigated the prescribing habits of individual physicians.
- 42. McKinsey helped shape Purdue's OxyContin marketing, which misleadingly centered on freedom and peace of mind for users. The marketing was tailored to avoid running directly afoul of the Corporate Integrity Agreement, but it remained misleading given what Purdue and McKinsey knew about opioids. One advertisement said, "we sell hope in a bottle," despite the fact that both McKinsey and Purdue already understood the addiction problems associated with opioid use and abuse. McKinsey encouraged Purdue to tell doctors that OxyContin would give their patients "the best possible chance to live a full and active life."
- 43. McKinsey urged Purdue to train and incentivize its sales representatives to increase sales across the market for opioids, even if sales went to Purdue's competitors. This was intended to serve the Sackler family's goal of increasing the marketability of Purdue for potential mergers, but it had the effect of worsening the opioid crisis even beyond the portion of the crisis directly attributable to sales and use of OxyContin.

C. Project Turbocharge

44. The Corporate Integrity Agreement expired in 2012. With this restriction lifted, McKinsey devised additional marketing and sales strategies for Purdue to further increase OxyContin sales.

- 45. In the second half of 2013, McKinsey made recommendations to Purdue to increase OxyContin revenue, including "Turbocharging Purdue's Sales Engine."
- 46. McKinsey's "Project Turbocharge" recommendations included revising the existing process for targeting high-prescribing physicians, with a shift from targeting solely on the basis of prescription deciles to considering additional factors. Based on its analysis, McKinsey told Purdue that "[t]here is significant opportunity to slow the decline of OxyContin by calling on more high-value physicians" and that "[t]he revenue upside from sales re-targeting and adherence could be up to \$250 million."
- 47. Also as part of the "Project Turbocharge" recommendations, McKinsey determined and advised Purdue that the top half of prescribing physicians "write on average 25 times more scripts per prescriber" than the lower half.
- 48. Despite knowing that then recently expired Corporate Integrity Agreement required Purdue to refrain from improperly incentivizing OxyContin sales, McKinsey also recommended increasing incentive compensation for incremental OxyContin prescriptions, advising Purdue that "[r]evision to incentive comp could better align reps to Purdue's economics."
- 49. At the same time, McKinsey recommended decreasing training by six days a year in order to allow employees more time to make sales calls. Meanwhile, McKinsey advised Purdue to exercise closer control over its sales staff in order to generate more efficient physician targeting.
- 50. Physician targeting proved effective. McKinsey advised Purdue that visiting high-prescribing doctors many times per year increased sales.

- 51. McKinsey recommended that Purdue circumvent pharmacies entirely with a mail order program because enforcement by federal regulators was decreasing OxyContin dispensing through Walgreens.
- 52. At the board level, McKinsey urged the Sacklers to impose a "revenue growth goal" on management.
- 53. With McKinsey's ongoing involvement and advice, Purdue implemented McKinsey's recommendations discussed above, but rebranded the program from Project Turbocharge to Evolve to Excellence.
- 54. McKinsey's efforts had the effect the Sacklers had asked McKinsey to achieve. Sales of OxyContin tripled in the years following the 2007 guilty plea, despite the restrictions imposed by the Corporate Integrity Agreement. According to the U.S. Department of Justice, "[f]rom 2010 to 2018, Purdue's profits were almost entirely driven by its success in selling OxyContin."
- 55. The Sacklers did not sell Purdue or enter into a merger, but their goal of extracting wealth from the business was realized. The Sackler family has withdrawn over \$10 billion from Purdue since 2008, including \$1.7 billion in 2009 alone. These distributions were made possible by McKinsey's services and came at the expense of a deepening national opioid crisis.
 - D. McKinsey Knew About the Dangers of Opioids and Acted to Maximize OxyContin Prescriptions Anyway
- 56. McKinsey has a long history of consulting in the pharmaceutical industry. In addition to its work with Purdue, McKinsey has performed "opioid-related work" for Johnson & Johnson, Endo International, and Mallinckrodt Pharmaceuticals. For instance, a McKinsey

PowerPoint presentation prepared for Johnson & Johnson recommended that Johnson & Johnson aggressively target and influence doctors treating back pain in order to increase opioid sales.

- 57. Purdue's 2007 guilty plea put McKinsey on notice of Purdue's misconduct. By that time, McKinsey had access to public information indicating that OxyContin and other opioids pose significant risk of addiction and misuse.
- 58. McKinsey's presentations to Purdue in 2013 included extensive discussion of doctors' concerns about opioid misuse and side effects, demonstrating McKinsey's awareness of the dangers of opioids. Rather than working to limit these disastrous effects, McKinsey treated doctors' misgivings as obstacles to confront with new messaging.
- 59. McKinsey continued working with Purdue long after the severity of the opioid crisis was well known. In 2017, McKinsey proposed that Purdue pay CVS and other distributors of OxyContin rebates "for every OxyContin overdose attributable to pills they sold."
 - 60. A former McKinsey consultant described McKinsey's work with Purdue:

[T]he banality of evil, M.B.A. edition. . . . They knew what was going on. And they found a way to look past it, through it, around it, so as to answer the only questions they cared about: how to make the client money, and when the walls closed in, how to protect themselves.

61. In a 2018 email thread, apparently fearing consequences for McKinsey's work with Purdue, two McKinsey senior partners who had participated in McKinsey's work advising Purdue discussed deleting documents related to opioids.

E. Purdue's 2020 Guilty Plea and McKinsey's Recent Statement

62. In October of 2020, Purdue once again reached an agreement (the "2020 Settlement Agreement") with the U.S. Department of Justice to enter a guilty plea related to its marketing of OxyContin. The agreement includes \$8.3 billion in penalties from Purdue and \$225 million from the Sackler family.

- 63. In the 2020 Settlement Agreement, Purdue pleaded guilty to defrauding health agencies, violating anti-kickback laws, paying illegal kickbacks to doctors, and "using aggressive marketing tactics to convince doctors to unnecessarily prescribe opioids—frivolous prescriptions that experts say helped fuel a drug addiction crisis that has ravaged America for decades."
- 64. The 2020 Settlement Agreement was entered by Purdue and the United States government. It explicitly states that it does not release Purdue of "[a]ny liability for claims of the states or Indian tribes."
- 65. The 2020 Settlement Agreement includes a provision specifically reserving claims regarding "[a]ny liability of entities other than the [Purdue Bankruptcy] Debtors, including consultants."
- 66. On December 5, 2020, McKinsey issued the following statement regarding its work with Purdue:

December 5, 2020—As we look back at our client service during the opioid crisis, we recognize that we did not adequately acknowledge the epidemic unfolding in our communities or the terrible impact of opioid misuse and addiction on millions of families across the country. That is why last year we stopped doing any work on opioid-specific business, anywhere in the world.

Our work with Purdue was designed to support the legal prescription and use of opioids for patients with legitimate medical needs, and any suggestion that our work sought to increase overdoses or misuse and worsen a public health crisis is wrong. That said, we recognize that we have a responsibility to take into account the broader context and implications of the work that we do. Our work for Purdue fell short of that standard.

We have been undertaking a full review of the work in question, including into the 2018 email exchange which referenced potential deletion of documents. We continue to cooperate fully with the authorities investigating these matters.

67. In recent weeks, McKinsey has settled opioid-related claims with 49 states, the District of Columbia, and five U.S. territories.

- F. Impact of Opioid Abuse, Addiction, and Diversion on American Indians and Alaska Natives
- 68. There are 574 federally recognized Tribes in the United States, located within the borders of 35 states. They are diverse in terms of their size, geography, culture, and resources, but they share a status as sovereign governments responsible for the health and well-being of their citizens.
 - 69. Native Americans have disproportionately borne the toll of the opioid crisis.
 - 70. Native Americans suffer the highest per capita rate of opioid overdoses.
- 71. According to the IHS, there has been a "four-fold increase in opioid overdoses from 1999 to 2013 among American Indians and Alaska Natives . . . [T]wice the rate of the general U.S. population."
- 72. The CDC reported that the "rates of death from prescription opioid overdose among American Indian or Alaska Natives increased almost four-fold from 1.3 per 100,000 in 1999 to 5.1 per 100,000 in 2013." By 2014, the CDC reported "8.4 per 100,000 Native Americans were dying of opioid overdoses, the highest number of any racial demographic."
- 73. In 2014, Native Americans had the highest death rate from opioid overdoses out of any ethnic group in the country.
- 74. The impact on Native American children is particularly devastating. In a study conducted to examine substance-related disorders among adolescents across racial and ethnic groups, "Racial/Ethnic Variations in Substance-Related Disorders Among Adolescents in the United States," the authors found of 72,561 adolescents aged 12 to 17 years:
- a. Analgesic opioids were the second most commonly used illegal drug after marijuana;

- b. Analgesic opioid use was comparatively prevalent among Native American adolescents (9.7%);
- c. Native Americans have the highest prevalence of use (47.5%) and disorders (15.0%); and
 - d. 31.5% of Native Americans had substance-related disorders.

75. The study concluded:

Native Americans have the highest prevalence of substance use and substance-related disorders, adding to evidence that young Native Americans are a vulnerable group facing numerous stressors, trauma, and health disparities (e.g., highest rate of suicide, underfunded systems of care, and lack of access to appropriate care). The results herein highlight a critical need for intervention to reduce their burdens from substance use and for policies to address presently underfunded systems of care and improve infrastructures linking behavioral and primary health care services.

(footnotes omitted).

- 76. The CDC reported that approximately 1 in 10 Native American youths ages 12 or older used prescription opioids for nonmedical purposes in 2012, double the rate for White youth.
- 77. The fact that adolescents are able to easily obtain prescription opioids through the black market created by opioid diversion highlights the direct impact on Plaintiffs and their communities by Purdue and McKinsey's actions and inactions.
- 78. Even the youngest citizens of tribal communities bear the consequences of the opioid abuse epidemic fueled by McKinsey's conduct working with Purdue and other manufacturers of opioids. Between 2009 and 2012, "American Indian women [were] 8.7 times more likely to be diagnosed with maternal opiate dependence or abuse during pregnancy," compared to non-Hispanic women. That translates into 1 in 10 pregnancies among American

Indian women. As a result, many tribal infants suffer from opioid withdrawal and Neonatal Abstinence Syndrome (NAS).

- 79. Infants suffering from NAS are separated from their families and placed into the custody of the tribal child welfare services or receive other government services so they can be afforded medical treatment and be protected from drug-addicted parents.
- 80. The impact of NAS can be lifelong. Most NAS infants are immediately transferred to a neonatal intensive care unit for a period of days, weeks, or even months. NAS can also require an emergency evacuation for care to save the infant's life. Such emergency transportation costs thousands of dollars for each occurrence.
- 81. Many NAS infants have short-term and long-term developmental issues that prevent them from meeting basic cognitive and motor-skills milestones. Many will suffer from vision and digestive issues; some are unable to attend full days of school. These disabilities follow these children through elementary school and beyond.
- 82. Many of the parents of these children continue to relapse into prescription opioid use and abuse, having an impact on their families and tribal communities for financial and other support.
- 83. Opioid diversion also contributes to a range of social problems including physical and mental consequences, crime, delinquency, and mortality. Opioid abuse has also resulted in an explosion in heroin use. Almost 80% of those who used heroin in the past year previously abused prescription opioids. Other adverse social outcomes include child abuse and neglect, family dysfunction, criminal behavior, poverty, property damage, unemployment, and despair.
 - G. The Impact of McKinsey's Work with Opioid Manufacturers on Plaintiffs
 - 84. Plaintiffs' own experience treating opioids illustrates these national trends.

- 85. Indeed, Plaintiffs are currently facing a public health crisis that threatens to undermine the safety and wellbeing of their entire Tribal communities. Overarching health, public safety, and law enforcement concerns relate to, among others, prescription opioid drug abuse and major crimes involving opioid and drug use.
- 86. The State of California is experiencing the impacts of the epidemic. Certain regions of California have death rates approaching the highest in the country. Communities throughout California have been devastated by the opioid epidemic brought about by Defendant's conduct, particularly in rural communities like those in North San Diego County. The opioid overdose death rate in California in 2019 was 7.9 per 100,000, but in San Diego County the rate was 8.92 per 100,000.
- 87. Overall, San Diego County had 1,342,904 opioid prescriptions in 2019.⁵ The annual prescribing rate during that period was 402.27 per 1,000 residents, which represents a 21% decrease in prescribing from 2017.⁶ County-wide, there were 314 deaths due to all opioid-related overdoses in 2019.⁷

⁴ Cal. Dep't of Pub. Health et al., California Opioid Overdose Surveillance Dashboard, California Dashboard, https://skylab.cdph.ca.gov/ODdash/ (select California Dashboard; then select Graph) (last visited Mar. 11, 2021).

⁵ Cal. Dep't of Pub. Health et al., San Diego Opioid Overdose Snapshot: 2017-Q1 through 2020 Q3 2, California Opioid Overdose Surveillance Dashboard, https://skylab.cdph.ca.gov/ODdash/ (select County Dashboard; then select San Diego; then download country report) (last visited Mar. 11, 2021).

 $^{^{6}}$ Id

⁷ *Id.* at 1.

- 88. San Diego County has the largest number of tribes and reservations of any county in the United States, with 18 federally recognized reservations and 17 tribal governments. The Tribe has a reservation in northern San Diego County, about 40 miles northeast of San Diego and on the San Luis Rey River.
- 89. In 2019 in California, the rate of opioid deaths for Native people was higher than any other group: 15.68 per 100,000—twice the statewide rate. The same holds true in San Diego County, where that rate is 34.63 per 100,000. The face of the opioid crisis in San Diego County is truly a Native one.
- 90. The opioid epidemic is devastating the people, institutions, and resources of the Plaintiffs' Tribal communities, causing substantial loss of resources, economic damages, addiction, disability, and harm to the health and welfare of those communities.
- 91. Burdens and costs related to the misuse, addiction, and/or overdose of opioids the Plaintiffs have borne include, but are not limited to, the following:
 - a. Emergency medical visits for opioid misuse, addiction, and/or overdose.
- b. Emergency medical visits for infections, injuries, illnesses, and drug-seeking related to opioid misuse, addiction, and/or overdose.
 - c. Hospitalizations related to the misuse, addiction, and/or overdose of opioids.

⁸ 2013 San Diego Integrated Regional Water Management Plan, Section 4.1., https://www.sdirwmp.org/pdf/SDIRWM_04_Tribal_Nations_Sep2013.pdf (last visited Mar. 11, 2021).

⁹ Cal. Dep't of Pub. Health et al., *supra* note 4 (select California Dashboard; then select Display Options; select View Indicators by Race/Ethnicity; select Native American/Alaska Native; select Table).

¹⁰ *Id.* (select Graph).

- d. Increased burdens and costs of administering and staffing of social services, including case workers and resources to aid (1) those members of the Plaintiffs' communities addicted to and/or dependent on opioids; (2) reintegration of Tribal and village members into their family and community following treatment; (3) the abused or neglected children and elders whose guardians are addicted to and/or dependent on opioids; and (4) the many foster or adoptive guardians who take on the role of caretaker in their absence.
 - e. Increased costs for testing of drug samples as part of the legal process.
- f. Care, education, and support of pregnant women addicted to opioids and of their children born with NAS, including ongoing educational and developmental support to address the long-term consequences of fetal opioid exposure; and
- g. Treatment of victims and criminal offenders, including holistic communitybased treatment programming and drug screening.
- 92. More and more Tribal resources are needed to combat these problems, leaving a diminished pool of already scarce resources to devote to positive societal causes that advance the health and wellness of the Tribe's members and IHC's service population. The prescription opioid crisis diminishes the Tribe's available workforce, decreases productivity, increases poverty, and requires greater governmental expenditures by the Tribe. It also undermines the ability of the Tribes to self-govern and to maintain and develop economic independence. Further, it requires IHC to continually increase the number of committed staff, facilities, activities, and financial resources to address and respond to the opioid epidemic impacting its service population.

H. Tolling of Statutes of Limitations

- 1. <u>Equitable Estoppel and Fraudulent Concealment</u>
- 93. McKinsey is equitably estopped from relying upon a statute of limitations defense because, alongside Purdue, McKinsey undertook active efforts to deceive the Plaintiffs and to purposefully conceal their unlawful conduct and fraudulently assure the public and Plaintiffs that they were undertaking efforts to comply with their obligations under State and federal controlled substances laws, all with the goal of protecting their registered manufacturer or distributor status in the State and to continue generating profits. Notwithstanding the allegations set forth above, McKinsey and Purdue affirmatively assured the public and Plaintiffs that they were working to curb the opioid epidemic.
- 94. McKinsey and Purdue were deliberate in taking steps to conceal their conspiratorial behavior and active role in the deceptive marketing and the oversupply of opioids through overprescribing and suspicious sales, all of which fueled the opioid epidemic.
- 95. McKinsey's consulting services were given confidentially, and both McKinsey and Purdue concealed the content of those services from the public.
- 96. McKinsey and Purdue also concealed from Plaintiffs the existence of Plaintiffs' claims by hiding their lack of cooperation with law enforcement and affirmatively seeking to convince the public that Purdue's legal duties to report suspicious sales had been satisfied through public assurances that they were working to curb the opioid epidemic. They publicly portrayed themselves as committed to working diligently with law enforcement and others to prevent diversion of these dangerous drugs and curb the opioid epidemic, and they made broad promises to change their ways insisting they were good corporate citizens. These repeated misrepresentations misled regulators, prescribers, and the public, including Plaintiffs, and

deprived Plaintiffs of actual or implied knowledge of facts sufficient to put Plaintiffs on notice of potential claims.

- 97. Plaintiffs did not discover the nature, scope, and magnitude of McKinsey's misconduct, and its full impact on Plaintiffs, and could not have acquired such knowledge earlier through the exercise of reasonable diligence.
- 98. Purdue and McKinsey's campaign to misrepresent and conceal the truth about the opioid drugs that they were aggressively pushing on Plaintiffs deceived the medical community, consumers, and Plaintiffs.
- 99. Further, Purdue and other opioid manufacturers also concealed and prevented discovery of information, including data from the ARCOS database.
- 100. McKinsey intended that their actions and omissions made with Purdue would be relied upon, including by Plaintiffs. Plaintiffs did not know and did not have the means to know the truth, due to McKinsey and Purdue's actions and omissions.
- 101. Plaintiffs reasonably relied on McKinsey and Purdue's affirmative statements regarding their purported compliance with their obligations under the law and consent orders.
 - 2. <u>McKinsey and Purdue Persisted in The Fraudulent Scheme Despite a Guilty Plea and Large Fine.</u>
- 102. In May 2007, Purdue and three of its executives pled guilty to federal charges of misbranding OxyContin in what the company acknowledged was an attempt to mislead doctors about the risk of addiction. Purdue was ordered to pay \$600 million in fines and fees. In its plea, Purdue admitted that its promotion of OxyContin was misleading and inaccurate, misrepresented the risk of addiction, and was unsupported by science. Additionally, Michael Friedman, the company's president, pled guilty to a misbranding charge and agreed to pay \$19 million in fines; Howard R. Udell, Purdue's top lawyer, also pled guilty and agreed to pay \$8

million in fines; and Paul D. Goldenheim, its former medical director, pled guilty as well and agreed to pay \$7.5 million in fines.

- 103. Nevertheless, even after the settlement, Purdue continued to pay doctors on speakers' bureaus to promote the liberal prescribing of OxyContin for chronic pain and to fund seemingly neutral organizations to disseminate the message that opioids were non-addictive, as well as other misrepresentations. At least until early 2018, Purdue continued to deceptively market the benefits of opioids for chronic pain while diminishing the associated dangers of addiction. After Purdue made its guilty plea in 2007, it assembled an army of lobbyists to fight any legislative actions that might encroach on its business. Between 2006 and 2015, Purdue and other painkiller producers, along with their associated nonprofits, spent nearly \$900 million dollars on lobbying and political contributions—eight times what the gun lobby spent during that period. McKinsey participated extensively in these actions and provided Purdue with strategies and assistance to maximize sales as described in this Complaint.
- 104. As all of the government actions against the Purdue and McKinsey demonstrate, McKinsey knew that the actions it took with Purdue were unlawful, and yet deliberately proceeded in order to increase Purdue's sales and profits and in turn to serve McKinsey's financial interests.

V. FACTUAL ALLEGATIONS PERTAINING TO CLAIMS UNDER THE RACKETEER INFLUENCED AND CORRUPT ORGANIZATIONS (RICO) ACT: THE OPIOID MARKETING ENTERPRISE

A. The Common Purpose and Scheme of the Opioid Marketing Enterprise

105. Knowing that their products were highly addictive, ineffective, and unsafe for the treatment of long-term chronic pain, non-acute, and non-cancer pain, McKinsey, who participated in the marketing and sale of opioids as described in this Complaint, and manufacturers of opioids, including Purdue, Johnson & Johnson, Cephalon, Janssen, Endo, and

Mallinckrodt (collectively, including McKinsey, the "Opioid Marketing Enterprise Members"), formed an association-in-fact enterprise and engaged in a scheme to unlawfully increase their profits and sales, and grow their share of the prescription painkiller market, through repeated and systematic misrepresentations about the safety and efficacy of opioids for treating long-term chronic pain.

- 106. In order to unlawfully increase the demand for opioids, the Opioid Marketing Enterprise Members formed an association-in-fact enterprise (the "Opioid Marketing Enterprise"). Through their personal relationships, the members of the Opioid Marketing Enterprise had the opportunity to form and take actions in furtherance of the Opioid Marketing Enterprise's common purpose. The Opioid Marketing Enterprise Members' substantial financial contribution to the Opioid Marketing Enterprise, and the advancement of opioids-friendly messaging, fueled the U.S. opioids epidemic.
- Enterprise, concealed the true risks and dangers of opioids from the medical community and the public, including Plaintiffs, and made misleading statements and misrepresentations about opioids that downplayed the risk of addiction and exaggerated the benefits of opioid use. The misleading statements included: (1) that addiction is rare among patients taking opioids for pain; (2) that addiction risk can be effectively managed; (3) that symptoms of addiction exhibited by opioid patients are actually symptoms of an invented condition the Opioid Marketing Enterprise Members named "pseudoaddiction"; (4) that withdrawal is easily managed; (5) that increased dosing presents no significant risks; (6) that long-term use of opioids improves function; (7) that the risks of alternative forms of pain treatment are greater than the adverse effects of opioids; (8) that use of time-released dosing prevents addiction; (9) that abuse-deterrent formulations

provide a solution to opioid abuse; and (10) that opioids would bring patients freedom and peace of mind.

- 108. The scheme devised, implemented, and conducted by the Opioid Marketing Enterprise Members was a common course of conduct designed to ensure that the Opioid Marketing Enterprise Members unlawfully increased their sales and profits through concealment and misrepresentations about the addictive nature and effective use of the Opioid Marketing Enterprise Members' drugs. The Opioid Marketing Enterprise Members acted together for a common purpose and perpetuated the Opioid Marketing Enterprise's scheme, including through the unbranded promotion and marketing network as described above.
- 109. There was regular communication between the Opioid Marketing Enterprise Members in which information was shared, misrepresentations were coordinated, and payments were exchanged. The Opioid Marketing Enterprise Members functioned as a continuing unit for the purpose of implementing the Opioid Marketing Enterprise's scheme and common purpose, and each agreed and took actions to hide the scheme and continue its existence.
- 110. As public scrutiny and media coverage focused on how opioids ravaged communities throughout the United States, McKinsey did not challenge Purdue or other manufacturers' misrepresentations, seek to correct their previous misrepresentations, terminate their role in the Opioid Marketing Enterprise, nor disclose publicly that the risks of using opioids for chronic pain outweighed their benefits and were not supported by medically acceptable evidence. Instead, McKinsey continued to participate in the Opioid Marketing Enterprise for financial gain.
- 111. The Opioid Marketing Enterprise Members engaged in certain discrete categories of activities in furtherance of the common purpose of the Opioid Marketing Enterprise. The

Opioid Marketing Enterprise's conduct in furtherance of the common purpose of the Opioid Marketing Enterprise involved misrepresentations regarding the risk of addiction and safe use of prescription opioids for long-term chronic pain, including targeting physicians with misleading claims.

- 112. The impact of the Opioid Marketing Enterprise's scheme is still in place—*i.e.*, opioids continue to be prescribed and used for chronic pain throughout the area of the Plaintiffs, and the epidemic continues to injure Plaintiffs and consume Plaintiffs' resources.
- 113. As a result, it is clear that the Opioid Marketing Enterprise Members, including McKinsey, were each willing participants in the Opioid Marketing Enterprise, had a common purpose and interest in the object of the scheme, and functioned within a structure designed to effectuate the Enterprise's purpose.

B. The Conduct of the Opioid Marketing Enterprise Violated Civil RICO

- 114. From at least 2004 to the present, each of the Opioid Marketing Enterprise

 Members exerted control over the Opioid Marketing Enterprise and participated in the operation
 or management of the affairs of the Opioid Marketing Enterprise, directly or indirectly, in the
 following ways:
- a. Creating and providing a body of deceptive, misleading, and unsupported medical and popular literature about opioids that (i) understated the risks and overstated the benefits of long-term use; (ii) appeared to be the result of independent, objective research; and (iii) was thus more likely to be relied upon by physicians, patients, and payors;
- b. Creating and providing a body of deceptive, misleading, and unsupported electronic and print advertisements about opioids that (i) understated the risks and overstated the benefits of long-term use; (ii) appeared to be the result of independent, objective research; and (iii) was thus more likely to be relied upon by physicians, patients, and payors;

- c. Creating and providing a body of deceptive, misleading, and unsupported sales and promotional training materials about opioids that (i) understated the risks and overstated the benefits of long-term use; (ii) appeared to be the result of independent, objective research; and (iii) was thus more likely to be relied upon by physicians, patients, and payors;
- d. Devised and implemented marketing schemes that included targeting and misleading physicians, unlawfully incentivizing sales representatives to maximize prescriptions and dosages, and evading regulatory constraints;
- e. Disseminating many of their false, misleading, imbalanced, and unsupported statements through unbranded materials that appeared to be independent publications; and
- f. Using front groups and key opinion leaders (KOLs) to mislead the public about opioids.
- 115. The scheme devised and implemented by the Opioid Marketing Enterprise

 Members amounted to a common course of conduct intended to increase the Opioid Marketing

 Enterprise Members' sales from prescription opioids by encouraging the prescribing and use of
 opioids for long-term chronic pain. The scheme was a continuing course of conduct, and many
 aspects of it continue through to the present.

C. Pattern of Racketeering Activity

- 116. The Opioid Marketing Enterprise Members' scheme described herein was perpetrated, in part, through multiple acts of mail fraud and wire fraud, constituting a pattern of racketeering activity as described herein.
- 117. The pattern of racketeering activity used by the Opioid Marketing Enterprise

 Members and the Opioid Marketing Enterprise likely involved thousands of separate instances of
 the use of the U.S. Mail or interstate wire facilities in furtherance of the unlawful Opioid

 Marketing Enterprise, including essentially uniform misrepresentations, concealments, and

material omissions regarding the beneficial uses and non-addictive qualities for the long-term treatment of chronic, non-acute, and non-cancer pain, with the goal of profiting from increased sales of the Opioid Marketing Enterprise Members' drugs induced by consumers, prescribers, regulators, and Plaintiffs' reliance on the Opioid Marketing Enterprise Members' misrepresentations.

- 118. Each of these fraudulent mailings and interstate wire transmissions constitutes racketeering activity, and collectively, these violations constitute a pattern of racketeering activity, through which the Opioid Marketing Enterprise Members defrauded and intended to defraud Plaintiffs and other intended victims.
- 119. The Opioid Marketing Enterprise Members devised and knowingly carried out an illegal scheme and artifice to defraud by means of materially false or fraudulent pretenses, representations, promises, or omissions of material facts regarding the safe, non-addictive, and effective use of opioids for long-term chronic, non-acute and non-cancer pain. The Opioid Marketing Enterprise Members and members of the Opioid Marketing Enterprise knew that these representations violated the FDA-approved use of these drugs and were not supported by actual evidence. The Opioid Marketing Enterprise Members intended that their common purpose and scheme to defraud would, and did, use the U.S. Mail and interstate wire facilities, intentionally and knowingly with the specific intent to advance, and for the purpose of executing, their illegal scheme.
- 120. By intentionally concealing the material risks and affirmatively misrepresenting the benefits of using opioids for chronic pain to prescribers, regulators, and the public, including Plaintiffs, the Opioid Marketing Enterprise Members engaged in a fraudulent and unlawful course of conduct constituting a pattern of racketeering activity.

- 121. The Opioid Marketing Enterprise Members' use of the U.S. Mail and interstate wire facilities to perpetrate the opioids marketing scheme involved thousands of communications, publications, representations, statements, electronic transmissions, payments, including, *inter alia*:
- a. Marketing materials about opioids, and their risks and benefits, which the Opioid Marketing Enterprise Members sent to health care providers, transmitted through the internet and television, published, and transmitted to front groups and KOLs located across the country and Plaintiffs;
- b. Written representations and telephone calls among the Opioid Marketing Enterprise Members, and between the Opioid Marketing Enterprise Members and front groups, regarding the misrepresentations, marketing statements, and claims about opioids, including the non-addictive, safe use of chronic long-term pain generally;
- c. Written representations and telephone calls among the Opioid Marketing Enterprise Members, and between the Opioid Marketing Enterprise Members and KOLs, regarding the misrepresentations, marketing statements, and claims about opioids, including the non-addictive, safe use of chronic long-term pain generally;
- d. E-mails and telephone and written communications among the Opioid Marketing Enterprise Members, and between the Opioid Marketing Enterprise Members and the front groups, agreeing to or implementing the opioids marketing scheme;
- e. E-mails and telephone and written communications among the Opioid

 Marketing Enterprise Members, and between the Opioid Marketing Enterprise Members and the

 KOLs, agreeing to or implementing the opioids marketing scheme;

- f. Communications among the Opioid Marketing Enterprise Members and between the Opioid Marketing Enterprise Members, front groups, and the media regarding publication, drafting of treatment guidelines, and the dissemination of the same as part of the Opioid Marketing Enterprise;
- g. Communications among the Opioid Marketing Enterprise Members and between the Opioid Marketing Enterprise Members, KOLs, and the media regarding publication, drafting of treatment guidelines, and the dissemination of the same as part of the Opioid Marketing Enterprise;
- h. Written and oral communications directed to Plaintiffs and/or their Tribal citizens and service populations that fraudulently misrepresented the risks and benefits of using opioids for chronic pain; and
- Receipts of increased profits sent through the U.S. Mail and interstate wire facilities—the wrongful proceeds of the scheme.
- 122. In addition to the above-referenced predicate acts, it was intended by and foreseeable to the Opioid Marketing Enterprise Members that the front groups and the KOLs would distribute publications through the U.S. Mail and by interstate wire facilities and, in those publications, claim that the benefits of using opioids for chronic pain outweighed the risks of doing so.
- 123. To achieve the common goal and purpose of the Opioid Marketing Enterprise, the Opioid Marketing Enterprise Members and members of the Opioid Marketing Enterprise hid from the consumers, prescribers, regulators, and the Plaintiffs: (a) the fraudulent nature of the Opioid Marketing Enterprise Members' marketing scheme; (b) the fraudulent nature of statements made by the Opioid Marketing Enterprise Members and by their KOLs, front groups,

and other third parties regarding the safety and efficacy of prescription opioids; and (c) the true nature of the relationship between the members of the Opioid Marketing Enterprise.

- 124. The Opioid Marketing Enterprise Members and each member of the Opioid Marketing Enterprise agreed, with knowledge and intent, to the overall objective of the Opioid Marketing Enterprise Members' fraudulent scheme and participated in the common course of conduct to commit acts of fraud and indecency in marketing prescription opioids.
- 125. Indeed, for the Opioid Marketing Enterprise Members' fraudulent scheme to work, each of them had to agree to implement similar tactics regarding fraudulent marketing of prescription opioids. This conclusion is supported by the fact that opioid manufacturers among the Opioid Marketing Enterprise Members financed, supported, and worked through the same KOLs and front groups and often collaborated on and mutually supported the same publications, continuing medical education activities, presentations, and prescription guidelines.

The Opioid Marketing Enterprise Members' predicate acts all had the purpose of creating the opioid epidemic that substantially injured Plaintiffs' business and property, while simultaneously generating billion-dollar revenue and profits for the Opioid Marketing Enterprise Members. The predicate acts were committed or caused to be committed by the Opioid Marketing Enterprise Members through their participation in the Opioid Marketing Enterprise and in furtherance of its fraudulent scheme.

VI. CAUSES OF ACTION

- A. Racketeer Influenced and Corrupt Organizations (RICO), 18 U.S.C. § 1961, et seq.
- 126. Plaintiffs incorporate by reference all preceding paragraphs of this Complaint as if fully set forth herein and further allege as follows:

- 127. This claim is brought by Plaintiffs against Defendant McKinsey for actual damages, treble damages, and equitable relief under 18.U.S.C. § 1964, for violations of 18 U.S.C. § 1961, *et seq*.
- 128. At all relevant times, McKinsey is and has been a "person" under 18 U.S.C. § 1961(3) because it is capable of holding, and does hold, "a legal or beneficial interest in property."
- 129. Each Plaintiff is a "person," as that term is defined in 18 U.S.C. § 1961(3), and has standing to sue as it was and is injured in its business and/or property as a result of Defendant's wrongful conduct described herein.
- and/or participated in the conduct of an enterprise through a pattern of illegal activities (the predicate racketeering acts of mail and wire fraud) to carry out the common purpose of the Opioid Marketing Enterprise, *i.e.*, to unlawfully increase profits and revenues from the continued prescription and use of opioids for long-term chronic pain. Through the racketeering activities of the Opioid Marketing Enterprise, the Opioid Marketing Enterprise Members sought to further the common purpose of the Enterprise through a fraudulent scheme to change prescriber habits and public perception about the safety and efficacy of opioid use. In so doing, each of the Opioid Marketing Enterprise Members knowingly conducted and participated in the conduct of the Opioid Marketing Activities by engaging in mail and wire fraud in violation of 18 U.S.C. §§ 1962(c) and (d).
- 131. The Opioid Marketing Enterprise is an association-in-fact enterprise that consists of the Opioid Marketing Enterprise Members.

- 132. Each of the Opioid Marketing Enterprise Members conducted and participated in the conduct of the Opioid Marketing Enterprise by playing a distinct role in furthering the Enterprise's common purpose of increasing profits and sales through the knowing and intentional dissemination of false and misleading information about the safety and efficacy of long-term opioid use, and the risks and symptoms of addiction, in order to increase the market for prescription opioids by changing prescriber habits and public perceptions.
- 133. Specifically, the Opioid Marketing Enterprise Members each worked together to coordinate the Enterprise's goals and conceal their role, and the Enterprise's existence, from the public by, among other things, (i) funding, editing, and distributing publications that supported and advanced their false messages; (ii) funding KOLs to further promote their false messages; and (iii) tasking their own employees to direct deceptive marketing materials and pitches directly to physicians.
- 134. Further, each of the Opioid Marketing Enterprise Members had systematic links to and personal relationships with each other through joint participation in lobbying groups, trade industry organizations, contractual relationships, and continuing coordination of activities. The systematic links and personal relationships that were formed and developed allowed members of the Opioid Marketing Enterprise the opportunity to form the common purpose and agree to conduct and participate in the conduct of the Opioid Marketing Enterprise. Specifically, each of the Opioid Marketing Enterprise Members, including McKinsey working with and through the other Opioid Marketing Enterprise Members, coordinated their efforts through the same KOLs and front groups, based on their agreement and understanding that the front groups and KOLs were industry friendly and would work together with the Opioid Marketing Enterprise Members to advance the common purpose of the Opioid Marketing Enterprise, and each of the individuals

and entities who formed the Opioid Marketing Enterprise acted to enable the common purpose and fraudulent scheme of the Opioid Marketing Enterprise.

- 135. At all relevant times, the Opioid Marketing Enterprise: (a) had an existence separate and distinct from each Opioid Marketing Member; (b) was separate and distinct from the pattern of racketeering in which the Opioid Marketing Enterprise Members engaged; (c) was an ongoing and continuing organization consisting of individuals, persons, and legal entities, including each of the Opioid Marketing Enterprise Members; (d) was characterized by interpersonal relationships between and among each member of the Opioid Marketing Enterprise; and (e) had sufficient longevity for the enterprise to pursue its purpose and functioned as a continuing unit.
- 136. The Opioid Marketing Enterprise Members conducted and participated in the conduct of the Opioid Marketing Enterprise through a pattern of racketeering activity that employed the use of mail and wire facilities, in violation of 18 U.S.C. § 1341 (mail fraud) and § 1343 (wire fraud), to increase profits and revenue by changing prescriber habits and public perceptions in order to increase the prescription and use of prescription opioids and expand the market for opioids.
- 137. The Opioid Marketing Enterprise Members each committed, conspired to commit, and/or aided and abetted in the commission of at least two predicate acts of racketeering activity (*i.e.*, violations of 18 U.S.C. §§ 1341 and 1343) within the past ten years. The multiple acts of racketeering activity that the Opioid Marketing Enterprise Members committed, or aided and abetted in the commission of, were related to each other, posed a threat of continued racketeering activity, and therefore constitute a "pattern of racketeering activity." The racketeering activity was made possible by the Opioid Marketing Enterprise Members' regular use of the facilities,

services, distribution channels, and employees of the Opioid Marketing Enterprise, as well as the U.S. Mail and interstate wire facilities. The Opioid Marketing Enterprise Members participated in the scheme to defraud by using mail, telephones, and the Internet to transmit mailings and wires in interstate or foreign commerce.

- 138. The Opioid Marketing Enterprise Members' predicate acts of racketeering (18 U.S.C. § 1961(1)) include, but are not limited to:
- a. <u>Mail Fraud</u>: The Opioid Marketing Enterprise Members violated 18 U.S.C. § 1341 by sending or receiving, or by causing to be sent and/or received, materials via U.S. mail or commercial interstate carriers for the purpose of executing the unlawful scheme to design, manufacture, market, and sell the prescription opioids by means of false pretenses, misrepresentations, promises, and omissions.
- b. <u>Wire Fraud</u>: The Opioid Marketing Enterprise Members violated 18 U.S.C. § 1343 by transmitting and/or receiving, or by causing to be transmitted and/or received, materials by wire for the purpose of executing the unlawful scheme to design, manufacture, market, and sell the prescription opioids by means of false pretenses, misrepresentations, promises, and omissions.
- 139. Indeed, as summarized herein, the Opioid Marketing Enterprise Members used the mail and wires to send or receive thousands of communications, publications, representations, statements, electronic transmissions, and payments to carry out the Opioid Marketing Enterprise's fraudulent scheme.
- 140. Because the Opioid Marketing Enterprise Members disguised their participation in the Enterprise, and worked to keep even the Enterprise's existence secret so as to give the false appearance that their false messages reflected the views of independent third parties, many

of the precise dates of the Opioid Marketing Enterprise's uses of the U.S. Mail and interstate wire facilities (and corresponding predicate acts of mail and wire fraud) have been hidden and cannot be alleged without access to the books and records maintained by the Opioid Marketing Enterprise Members, front groups, and KOLs. Indeed, an essential part of the successful operation of the Opioid Marketing Enterprise alleged herein depended upon secrecy. However, Plaintiffs have described the occasions on which the Opioid Marketing Enterprise Members disseminated misrepresentations and false statements to consumers, prescribers, regulators, and Plaintiffs, and how those acts were in furtherance of the scheme.

- 141. Each instance of racketeering activity alleged herein was related, had similar purposes, involved the same or similar participants and methods of commission, and had similar results affecting similar victims, including consumers, prescribers, regulators, and Plaintiffs. The Opioid Marketing Enterprise Members calculated and intentionally crafted the scheme and common purpose of the Opioid Marketing Enterprise to ensure their own profits remained high. In designing and implementing the scheme, the Opioid Marketing Enterprise Members understood and intended that those in the distribution chain rely on the integrity of the pharmaceutical companies and ostensibly neutral third parties to provide objective and scientific evidence regarding the Opioid Marketing Enterprise Members' products.
- 142. The Opioid Marketing Enterprise Members' pattern of racketeering activity alleged herein and the Opioid Marketing Enterprise are separate and distinct from each other. Likewise, the Opioid Marketing Enterprise Members are distinct from the Opioid Marketing Enterprise.
- 143. The racketeering activities conducted by the Opioid Marketing Enterprise

 Members amounted to a common course of conduct, with a similar pattern and purpose, intended

to deceive consumers, prescribers, regulators, and the Plaintiffs. Each separate use of the U.S. Mail and/or interstate wire facilities employed by the Opioid Marketing Enterprise Members was related, had similar intended purposes, involved similar participants and methods of execution, and had the same results affecting the same victims, including consumers, prescribers, regulators, and the Plaintiffs. The Opioid Marketing Enterprise Members have engaged in the pattern of racketeering activity for the purpose of conducting the ongoing business affairs of the Opioid Marketing Enterprise.

- 144. Each of the Opioid Marketing Enterprise Members aided and abetted others in the violations of the above laws, thereby rendering them indictable as principals in the 18 U.S.C. §§ 1341 and 1343 offenses.
- 145. As described herein, the Opioid Marketing Enterprise Members engaged in a pattern of related and continuous predicate acts for years. The predicate acts constituted a variety of unlawful activities, each conducted with the common purpose of obtaining significant money and revenue from the marketing and sale of their highly addictive and dangerous drugs. The predicate acts also had the same or similar results, participants, victims, and methods of commission. The predicate acts were related and not isolated events.
- 146. The Opioid Marketing Enterprise Members' violations of law and their pattern of racketeering activity directly and proximately caused the Plaintiffs injury in their business and property. The Opioid Marketing Enterprise Members' pattern of racketeering activity logically, substantially, and foreseeably caused an opioid epidemic. Plaintiffs' injuries, as described below, were not unexpected, unforeseen, or independent. Rather, as Plaintiffs allege, the Opioid Marketing Enterprise Members knew that the opioids were unsuited to treatment of long-term chronic, non-acute, and non-cancer pain, or for any other use not approved by the FDA, and they

knew that opioids were highly addictive and subject to abuse. Nevertheless, the Opioid Marketing Enterprise Members engaged in a scheme of deception that utilized the mail and wires in order to carry out the Opioid Marketing Enterprises' fraudulent scheme, thereby increasing sales of their opioid products.

- 147. It was foreseeable and expected that the Opioid Marketing Enterprise Members' creation of and then participation in the Opioid Marketing Enterprise through a pattern of racketeering activities to carry out their fraudulent scheme would lead to a nationwide opioid epidemic, including increased opioid addiction and overdose.
- 148. Defendant's misleading marketing and failure to prevent prescription opioid diversion damaged the Plaintiffs and/or their Tribal citizens and service population. Defendant's misconduct has contributed to a range of social problems, including violence and delinquency. Adverse social outcomes include child neglect, family dysfunction, babies born addicted to opioids, criminal behavior, poverty, property damage, unemployment, and social despair. As a result, more and more of Plaintiffs' resources are devoted to addiction-related problems.
- 149. Specifically, the Opioid Marketing Enterprise Members' creation of, and then participation in, the Opioid Marketing Enterprise through a pattern of racketeering activities to carry out their fraudulent scheme has injured Plaintiffs in the form of substantial losses of money and property that logically, directly, and foreseeably arise from the opioid-addiction epidemic. Plaintiffs' injuries, as alleged throughout this Complaint and expressly incorporated herein by reference include:
- a. Costs for providing healthcare and medical care, additional therapeutic and prescription drug purchases, and other treatments for patients suffering from opioid-related addiction or disease, including overdoses and deaths;

- b. Costs of training first responders in the proper treatment of drug overdoses;
- c. Costs associated with providing first responders with naloxone—an opioid antagonist used to block the deadly effects of opioids in the context of overdose;
- d. Costs associated with emergency responses by first responders to opioid overdoses;
- e. Costs for providing mental-health services, treatment, counseling, rehabilitation services, and social services to victims of the opioid epidemic and their families;
- f. Costs for providing treatment of infants born with opioid-related medical conditions or born dependent on opioids due to drug use by mother during pregnancy;
- g. Costs associated with providing care for children whose parents suffer from opioid-related disability or incapacitation;
- h. Costs associated with removal of hazardous waste from Plaintiffs' community, including on Plaintiffs' real property.
- 150. Plaintiffs' injuries were directly and thus proximately caused by these racketeering activities because they were the logical, substantial, and foreseeable cause of Plaintiffs' injuries. But for the opioid-addiction epidemic the Opioid Marketing Enterprise Members created through their Opioid Marketing Enterprise, Plaintiffs would not have lost money or property, and the health and welfare of Plaintiffs and/or their Tribal citizens and service population would not have been injured.
- 151. The Plaintiffs are the most directly harmed entity, and there are no other Plaintiffs better suited to seek a remedy for the economic harms at issue here.
- 152. Plaintiffs seek all legal and equitable relief as allowed by law, including, *inter alia*, actual damages; treble damages; equitable and/or injunctive relief in the form of Court-

supervised corrective communication, actions, and programs; forfeiture as deemed proper by the Court; attorneys' fees; all costs and expenses of suit; and pre- and post-judgment interest, including, *inter alia*:

- a. Actual damages and treble damages, including pre-suit and post-judgment interest;
 - b. An order enjoining any further violations of RICO;
- c. An order enjoining any further violations of any statutes alleged to have been violated in this Complaint;
- d. An order enjoining the commission of any tortious conduct, as alleged in this Complaint;
- e. An order enjoining any future marketing or misrepresentations regarding the health benefits or risks of prescription opioids use except as specifically approved by the FDA;
- f. An order enjoining any future marketing of opioids through non-branded marketing including through front groups, KOLs, websites, or in any other manner alleged in this Complaint that deviates from the manner or method in which such marketing has been approved by the FDA;
- g. An order enjoining any future marketing to vulnerable populations, including but not limited to persons over the age of fifty-five, anyone under the age of twenty-one, and veterans;
- h. An order requiring McKinsey to publicly disclose all documents, communications, records, data, information, research, or studies related to its work with Purdue and other manufacturers of opioids;

- i. An order divesting McKinsey of any interest in and the proceeds of any work related to opioids;
 - j. Forfeiture as deemed appropriate by the Court; and
 - k. Attorneys' fees and all costs and expenses of suit.

B. Negligence under California Law

- 153. Plaintiffs incorporate by reference the preceding paragraphs of this Complaint as if fully set forth herein and further allege as follows:
- 154. The opioid epidemic was a direct, legal, and proximate result of McKinsey's negligence. As a direct, proximate, and legal result of said negligence, Plaintiffs suffered damages as alleged herein.
- 155. Through its work with Purdue and other opioid companies, McKinsey owed Plaintiffs duties of care. McKinsey's failure to comply with its duties of care proximately caused damage to Plaintiffs.
- 156. The negligence of McKinsey was a substantial factor in causing Plaintiffs' damages.
- 157. As a further direct and proximate result of McKinsey's negligence, the Plaintiff Tribe and its members suffered damages including, but not limited to, economic loss, business loss, emotional distress, annoyance, disturbance, shame, inconvenience, drug addiction and/or dependency, and neonatal abstinence syndrome. Similarly, the Plaintiff Tribal Organization, as a direct and proximate result of McKinsey's negligence, suffered damages including but not limited to the cost of unreimbursed care, increased costs of services, increased overhead costs, and increased public safety costs, among others as alleged throughout this Complaint.
- 158. There is moral blame attached to McKinsey as a result of the terrible injuries and suffering their misconduct caused, including the damage to Plaintiffs.

- 159. Public policy supports finding a duty of care in this circumstance, and a finding of a duty of care on McKinsey will also deter McKinsey from engaging in such behavior in the future.
- and subjected the Plaintiffs to cruel and unjust hardship in conscious disregard of their rights, constituting oppression, for which McKinsey must be punished by punitive and exemplary damages in an amount according to proof. McKinsey's conduct evidences a conscious disregard for the safety and welfare of others, including Plaintiff Tribe and Plaintiff Tribal Organization. McKinsey's conduct was and is despicable conduct and constitutes malice as defined by Civil Code § 3294. An officer, director, or managing agent of McKinsey personally committed, authorized, and/or ratified the despicable and wrongful conduct alleged in this Complaint.
- 161. Plaintiffs are entitled to an award of punitive damages sufficient to punish and make an example of the Defendant.

C. Public Nuisance - Cal. Civ. Code §§ 3479 and 3480

- 162. Plaintiffs incorporate by reference the preceding paragraphs as if fully set forth herein and further allege as follows:
- 163. Civil Code Section 3479 provides that "[a]nything that is injurious to health . . . or is indecent or offensive to the senses, or an obstruction to the free use of property, so as to interfere with the comfortable enjoyment of life or property . . . is a nuisance."
- 164. Civil Code Section 3480 defines a "public nuisance" as "one which affects at the same time an entire community or neighborhood, or any considerable number of persons, although the extent of the annoyance or damage inflicted upon individuals may be unequal."
- 165. Civil Code section 3490 states that "[n]o lapse of time can legalize a public nuisance, amounting to an actual obstruction of public right."

- 166. Pursuant to Section 731 of the Civil Code, this action is brought by the Plaintiffs to abate the public nuisance created by the Defendant.
- 167. Defendant has created or assisted in the creation of a condition that is injurious to the health and interferes with the comfortable enjoyment of life and property of entire communities or neighborhoods or of any considerable number of persons in the Tribe or IHC in violation of Civil Code Sections 3479 and 3480.
- 168. The public nuisance is substantial and unreasonable. Defendant's actions caused and continue to cause the public health epidemic described above, and that harm outweighs any offsetting benefit.
- 169. Defendant knew and should have known that their promotion of opioids was false and misleading and that their deceptive marketing scheme and other unlawful, unfair, and fraudulent actions would create or assist in the creation of the public nuisance—the opioid epidemic.
- 170. Defendant's actions were, at the very least, a substantial factor in opioids becoming widely available and widely used. Defendant's actions were, at the very least, a substantial factor in deceiving doctors and patients about the risks and benefits of opioids for the treatment of chronic pain. Without Defendant's actions, opioid use, misuse, abuse, and addiction would not have become so widespread, and the opioid epidemic that now exists would have been averted or much less severe.
- 171. The Defendant has breached its duties to the Plaintiffs by disseminating false and misleading information through Purdue regarding the dangers of opioid use and by targeting physicians likely to prescribe opioids for pain management despite the availability of other, less or non-addictive pain killers.

- 172. Working through Purdue, McKinsey unlawfully provided false or misleading material information about prescription opioids or unlawfully failed to use reasonable care or comply with statutory requirements in the distribution of prescription opioids.
- 173. McKinsey's acts and omissions created the opioid epidemic and thereby caused injury to the health of Plaintiffs and/or their Tribal citizens and service population and interfered with the comfortable enjoyment of life and property of others, specifically the Plaintiffs and/or their Tribal citizens and service population.
- 174. McKinsey's acts and omissions offend decency and include the illegal sales of controlled substances.
 - 175. McKinsey's acts and omissions render the Plaintiffs insecure.
- 176. The Plaintiffs did not consent, expressly or impliedly, to the wrongful conduct of Defendant.
- 177. As a direct and legal result of the conduct of McKinsey, Plaintiffs and their community and service population suffered harm that is different from the type of harm suffered by the general public. McKinsey's acts and omissions proximately caused injury to the Plaintiffs including, *inter alia*, recoupment of costs of providing or paying for the health care, pharmaceutical care, and other necessary services of the Plaintiffs, flowing from an ongoing and persistent public nuisance which Plaintiffs seek to abate.
- 178. McKinsey's acts and omissions affect the entire communities and service population of the Plaintiffs.
- 179. McKinsey also has a duty to abate the nuisance caused the by prescription opioid epidemic.

- 180. The public nuisance created, perpetuated, and maintained by McKinsey can be abated and further recurrence of such harm and inconvenience can be abated.
- 181. The hazardous condition which was created by and/or permitted to exist by McKinsey affected a substantial number of people at the same time within the general public, including Plaintiffs, and constituted a public nuisance under Civil Code §§ 3479 and 3480.
 - 182. McKinsey has failed to abate the nuisance they created.
- 183. The Plaintiffs seek economic damages from the Defendant as reimbursement for the costs associated with past efforts to eliminate the hazards to public health and safety.
- 184. Pursuant to Code of Civil Procedure § 731, the Plaintiffs seek an order both providing for abatement of the public nuisance that Defendant created or assisted in the creation of and enjoining Defendant from future violations of Civil Code §§ 3479 and 3480.
- 185. The Plaintiffs seek economic damages from the Defendant to pay for the costs to permanently eliminate the hazards to public health and safety and abate the public nuisance.
- 186. As a direct result of Defendant's conduct, the Plaintiffs and their communities have suffered actual injury and economic damages including, but not limited to, significant expenses for health, emergency, public safety, child protection, education and training, and other services.
- 187. McKinsey is liable to the Plaintiffs for the costs borne by Plaintiffs as a result of the opioid epidemic and for the costs of abating the nuisance created by McKinsey.

D. False Advertising Law (FAL) (Ca. Bus. & Prof. Code § 17500)

- 188. Plaintiffs incorporate by reference the preceding paragraphs as if fully set forth herein and further allege as follows:
 - 189. Section 17500 of the California Business and Professions Code states:

[It is] unlawful for any person, . . . corporation . . . with intent directly or indirectly to dispose of real or personal property . . . or to induce the public to enter into any obligation relating thereto, to make or disseminate or cause to be made or disseminated before the public in this state, . . . in any . . . manner or means whatever . . . any statement, concerning that real or personal property . . . which is untrue or misleading, and which is known, or which by the exercise of reasonable care should be known, to be untrue or misleading.

Cal. Bus. & Prof. Code § 17500.

- 190. As alleged above, Defendant's conduct working through Purdue was likely to deceive the Plaintiffs, who purchased or covered the purchase of opioids for chronic pain.
- 191. At times, places, and involving participants known exclusively to Defendant and other parties and concealed from Plaintiffs, Defendant violated the FAL by making and disseminating false or misleading statements about the use of opioids to treat chronic pain, or by causing false or misleading statements about opioids to be made or disseminated to the public.
- 192. Defendant violated the FAL by making statements to promote the use of opioids to treat chronic pain that omitted or concealed material facts and by failing to correct prior misrepresentations and omissions about the risks and benefits of opioids. Defendant's omissions, which are false and misleading in their own right, render even their seemingly truthful statements about opioids false and misleading.
- 193. Defendant's statements about the use of opioids to treat chronic pain were not supported by or were contrary to the scientific evidence, as confirmed by later pronouncements of the Centers for Disease Control and Prevention (CDC), the FDA, and by recent investigations based on that evidence.
- 194. Defendant knew and should have known at the time it made or disseminated the false and misleading statements or caused these statements to be made or disseminated that the statements were false or misleading and therefore likely to deceive the public.

195. In addition, Defendant knew and should have known that its false and misleading advertising created a false or misleading impression of the risks and benefits of long-term opioid use and would result in unnecessary and improper opioid prescriptions and use.

E. Unjust Enrichment

- 196. Plaintiffs incorporate by reference the preceding paragraphs of this Complaint as if fully set forth herein and further allege as follows:
- 197. As an expected and intended result of their conscious wrongdoing as set forth in this Complaint, McKinsey has profited and benefited from the increase in the distribution and purchase of opioids within Plaintiffs' communities, including from opioids foreseeably and deliberately diverted within and into Plaintiffs' communities.
- 198. The Plaintiffs have expended substantial amounts of money to fix or mitigate the societal harms caused by McKinsey's conduct.
- 199. Plaintiffs have conferred a benefit upon McKinsey by paying for what may be called McKinsey's externalities—the costs of the harm caused by McKinsey's negligent or otherwise unlawful distribution and sales practices.
- 200. Defendant is aware of this obvious benefit, and that retention of this benefit is unjust.
- 201. Plaintiffs have paid for the cost of McKinsey's externalities, and McKinsey has benefitted from those payments, because they allowed McKinsey to continue providing customers with a high volume of opioid products. Because of their deceptive marketing of prescription opioids, McKinsey obtained enrichment it would not otherwise have obtained. Because of its conscious failure to exercise due diligence in preventing diversion, McKinsey obtained enrichment it would not otherwise have obtained. The enrichment was without justification and Plaintiffs lack a remedy provided by law.

- 202. Defendant made substantial profits while fueling the prescription drug epidemic in the Plaintiffs' communities.
- 203. Defendant has been unjustly enriched by its negligent, intentional, malicious, oppressive, illegal, and unethical acts, omissions, and wrongdoing.
- 204. It would be inequitable to allow Defendant to retain benefit or financial advantage.
- 205. McKinsey's misconduct alleged in this case has caused ongoing and persistent harm to Plaintiffs.
- 206. The Plaintiffs demand judgment against the Defendant for restitution, disgorgement, and any other relief allowed in law or equity.

VII. PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray that the Court:

- a. Enter judgment against McKinsey and in favor of Plaintiffs;
- b. Award compensatory damages in an amount sufficient to compensate

 Plaintiffs fairly and completely for all damages, treble damages, pre-judgment and postjudgment interest as provided by law, and that such interest be awarded at the highest legal rate;
- c. Award damages caused by the opioid epidemic, including but not limited to (1) costs for providing medical care and additional therapeutic and prescription drug purchases, including costs of obtaining naloxone and suboxone, as well as other treatments for patients suffering from opioid-related addiction or disease, including overdoses and deaths; (2) costs for providing culturally informed treatment, counseling, education, and rehabilitation services; (3) costs for providing treatment of infants born with opioid-related medical conditions, including NAS; (4) costs for providing care for children whose parents suffer from opioid-related disability or incapacitation; (5) costs associated with social services, criminal justice, and

rehabilitation relating to the opioid epidemic; and (6) costs for providing transitional housing for those returning to the community;

- d. Enter orders and procedures to abate the nuisance created by McKinsey's wrongful conduct;
- e. Enjoin McKinsey from continuing or repeating the wrongful conduct alleged herein and from the publication and/or dissemination of false and misleading materials directly or indirectly;
- f. Award Plaintiffs their costs of suit, including reasonable attorneys' fees as provided by law;
- g. Award such further and additional relief as the Court may deem just and proper under the circumstances; and
- h. Grant Plaintiffs the right to amend their pleadings to conform to the evidence produced at trial.

VIII. JURY DEMAND

Plaintiffs demand a trial by jury on all issues so triable.

DATED this 13th day of April, 2021.

By: /s/ Adam P. Bailey

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